Bio|Nucleonics™
Inspired by Innovative Ingenuity™

Engaging the Private Sector; A Decade of Lesson Learned Navigating the Nuclear Pharma/Biotechnology Regulatory Maze

Collaborative Business-Government-NGO Relationships, Policies and Whole-of-Government Approach

Presented By:

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The G8 International Working Group (IWG)
3rd Brainstorming Roundtable About the Future of the Global Partnership
U.S. Southern Command, Doral, Florida

April 2012

TIME

THE OPPENHEIMER FILES
Revelations of a KGB spymaster

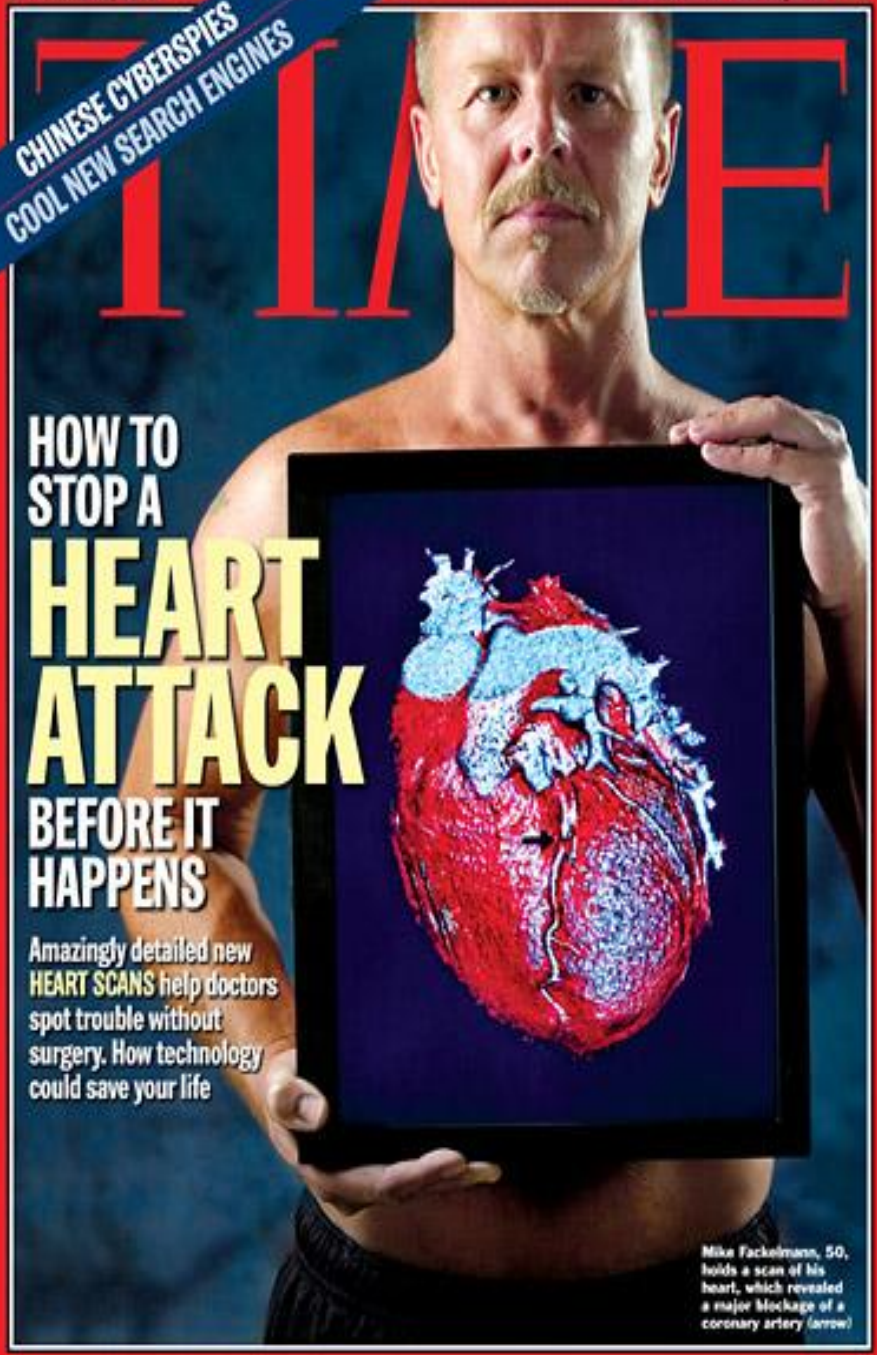
IT BEGINS as a single cell and grows into a merciless disease that claims more than half a million Americans a year. But scientists are steadily unlocking its mysteries, and the fight against it may now have reached a turning point. New discoveries promise better therapies and

HOPE IN THE WAR AGAINST CANCER

SEPTEMBER 5, 2005 www.time.com AOL Keyword: TIME

TIME

CHINESE CYBERSPIES
COOL NEW SEARCH ENGINES



HOW TO STOP A HEART ATTACK BEFORE IT HAPPENS

Amazingly detailed new HEART SCANS help doctors spot trouble without surgery. How technology could save your life

Mike Fackelmann, 50, holds a scan of his heart, which revealed a major blockage of a coronary artery (arrow)

Cancer Mortality Rates and Cost

The death rate from cancer in the U.S. has fallen only 5% over the past half century. The cure for cancer "has a long way to go." (New York Times, April 24, 2009).

The financial costs of cancer are great for the person with cancer and for society as a whole. In 2009, the National Institutes of Health estimated the 2008 U.S. annual costs of cancer were $228.1 billion. Direct medical costs were $ 93.2 billion. The cost of lost productivity due to illness: $ 18.8 billion. Indirect mortality costs (cost of lost productivity due to premature death): $116.1 billion. Cancer mortality rates in Russia, for example, are among highest in the world. Mortality from all cancers in Russian men (212 per 100 000 population) is higher than in western countries.

Cancer Risk

The Lifetime Probability of Developing Cancer for Men, 2005-2007*

Site	Risk
All sites†	1 in 2
Prostate	1 in 6
Lung and bronchus	1 in 13
Colon and rectum	1 in 19
Urinary bladder‡	1 in 26
Melanoma§	1 in 37
Non-Hodgkin lymphoma	1 in 43
Kidney	1 in 53
Leukemia	1 in 66
Oral Cavity	1 in 71
Stomach	1 in 91

* For those free of cancer at beginning of age interval.
† All Sites exclude basal and squamous cell skin cancers and in situ cancers except urinary bladder.
‡ Includes invasive and in situ cancer cases
§ Statistic for white men.
Source: DevCan: Probability of Developing or Dying of Cancer Software, Version 6.5.0 Statistical Research and Applications Branch, NCI, 2010. http://srab.cancer.gov/devcan

The Lifetime Probability of Developing Cancer for Women, 2005-2007*

Site	Risk
All sites†	1 in 3
Breast	1 in 8
Lung & bronchus	1 in 16
Colon & rectum	1 in 20
Uterine corpus	1 in 39
Non-Hodgkin lymphoma	1 in 52
Urinary bladder‡	1 in 87
Melanoma§	1 in 55
Ovary	1 in 72
Pancreas	1 in 71
Uterine cervix	1 in 147

* For those free of cancer at beginning of age interval.
† All Sites exclude basal and squamous cell skin cancers and in situ cancers except urinary bladder.
‡ Includes invasive and in situ cancer cases
§ Statistic for white women.
Source: DevCan: Probability of Developing or Dying of Cancer Software, Version 6.5.0 Statistical Research and Applications Branch, NCI, 2010. http://srab.cancer.gov/devcan

2012 Estimated U.S. Cancer Cases

Men 822,300	
Prostate	29%
Lung & bronchus	14%
Colon & rectum	9%
Urinary bladder	6%
Melanoma of skin	5%
Kidney & renal pelvis	5%
Non-Hodgkin lymphoma	4%
Oral cavity	3%
Leukemia	3%
Pancreas	3%
All Other Sites	19%

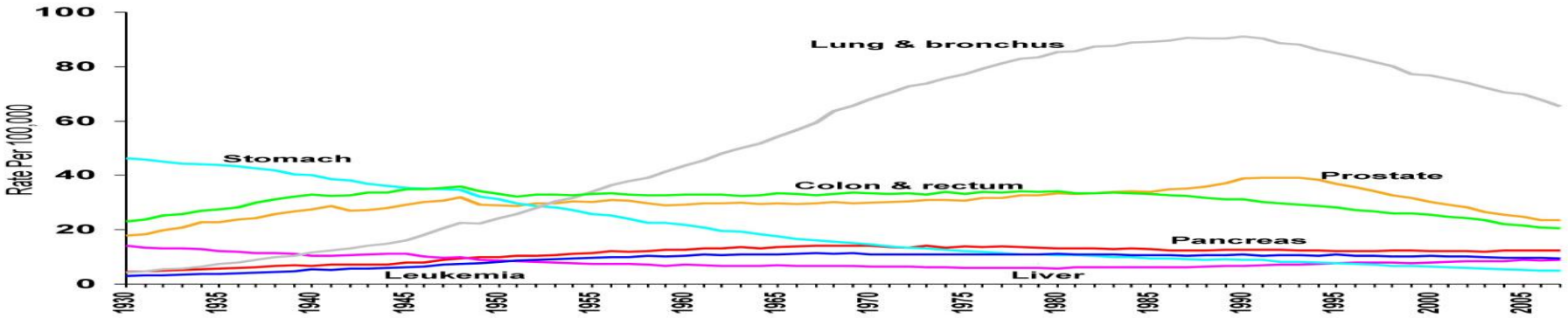
Women 774,370	
30%	Breast
14%	Lung & bronchus
9%	Colon & rectum
6%	Uterine corpus
5%	Thyroid
4%	Non-Hodgkin lymphoma
4%	Melanoma of skin
3%	Kidney & renal pelvis
3%	Ovary
3%	Pancreas
16%	All Other Sites

Source: American Cancer Society, 2011

Source: American Cancer Society, 2011.

*Excludes basal and squamous cell skin cancers and in situ carcinomas except urinary bladder.

Cancer Death Rates* Among Men, US, 1930-2007



*Age-adjusted to the 2000 US standard population.
Source: US Mortality Data 1960-2007, US Mortality Volumes 1930-1959, National Center for Health Statistics, Centers for Disease Control and Prevention.

Especially, Hope For Children

Trends in 5-year Relative Survival Rates for Childhood Cancer, Ages 0-14 yrs,1975-2006

*Based on follow up of patients through 2006
Source: Surveillance, Epidemiology, and End Results Program, 1975-2007, Division of Cancer Control and Population Sciences, National Cancer Institute, 2010.

Putin Sings at Federation Pediatric Oncology Charity Event In St. Petersburg

Isotopes In Medicine

DIAGNOSIS

in vitro

^{14}C
^{3}H
^{125}I
^{32}P
^{33}P

Others

in vivo

^{99}Mo-^{99m}Tc

^{201}Tl
^{123}I, ^{131}I
^{111}In
^{67}Ga
^{186}Re
^{81}Rb-^{81m}Kr
Others
ß$^{+}$ Emitters for PET
^{18}F, ^{11}C,^{13}N,^{15}O
^{86}Y, ^{124}I
^{68}Ge-^{68}Ga
^{82}Sr-^{82}Rb
^{89}Zr
^{64}Cu
Others

THERAPY

internal

systemic

^{131}I,^{90}Y
$^{89}Sr$$^{153}Sm$,
^{186}Re
^{188}W-^{188}Re
^{166}Ho,^{177}Lu,
Others
α-emitters:
^{225}Ac-^{213}Bi
^{211}At, ^{223}Ra ^{149}Tb
^{67}Cu
e^{-}-emitters:
^{125}I
^{32}P
Others

sources

Sealed Sources and Applicators:
^{192}Ir,
^{137}Cs
^{90}Sr
Others
Brachytherapy:
^{103}Pd,
^{125}I
^{131}Cs
^{67}Cu
Microspheres
^{90}Y
Others

external

Radio

^{60}Co
^{192}Ir

Gamma, Cyber Knife

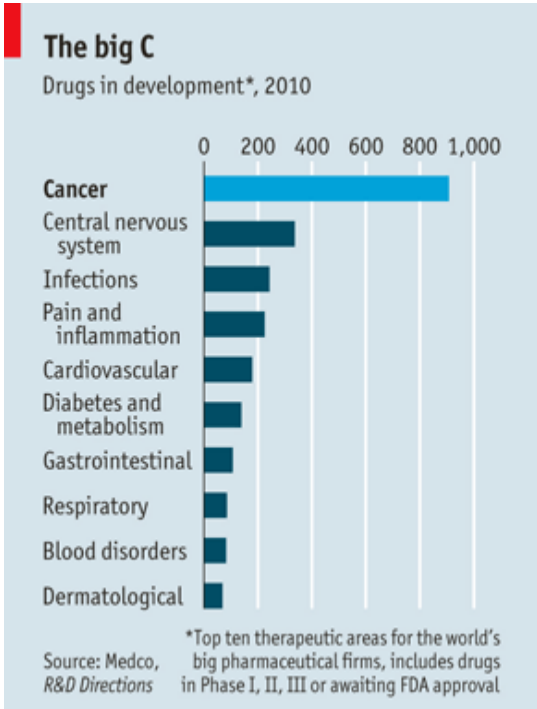
^{137}Cs
Blood Irradi-ation, Brachy-

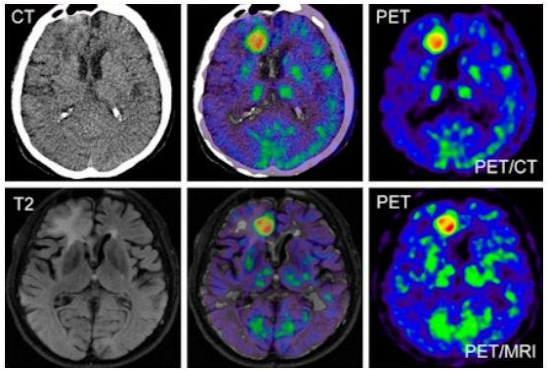
Radiopharmaceuticals

1 In Every 4 Patients Entering a U.S. Hospital Undergoes Some Form of Radioactive Diagnostic or Therapeutic Procedure

Medical imaging (SPECT, CT, PET, MRI or combination PET/CT) used in nuclear medicine is generally underpublicized as it does not carry the promise of cures; however the market is quite large.

Market

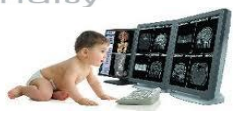




- The global imaging market was $20.7 billion in 2010.
- Global market for radiopharmaceuticals is projected to reach $6.6 billion by 2016.
- Sales of contrast media for MRI and CT will rise to $2.94 billion by 2013.
- Although molecular imaging holds great promise and market potential, significant barriers to market entry, including getting through the regulatory approval process.
- Growth potential providing opportunities for companies to enter this market, both through acquisitions or by licensing technologies
- Top PET oncology applications are respiratory, breast cancer, lymphoma and colorectal cancer. Neurology and cardiology applications make up the rest, likely to become a much larger proportion of PET studies, as tracers for Alzheimer's disease and cardiovascular disease are approved.
- Imaging agent market generally underpublicized as does not carry promise of cures. However market is quite large and number of companies engaged in manufacturing, few constituting a highly specialized and profitable market segment, vigorously expanding for nearly two decades with few signs of saturation.
- Radiopharmaceuticals provides a demonstrated growth opportunity based on rising numbers of scans performed. There is a very large market as well as savings in lives and healthcare dollars spent on therapy is why insurers' willingness to pay for diagnostic tests.

Sources: Global Industry Analysts, World Nuclear Association, Bio-Tech Systems, Markets and Markets, Frost & Sullivan

What is a PET Or Other Scan (SPECT, CT, MRI)?



In a 2008, U.S. Congressional report, Medicare imaging costs more than doubled to $14.1 billion from 2000 to 2006.

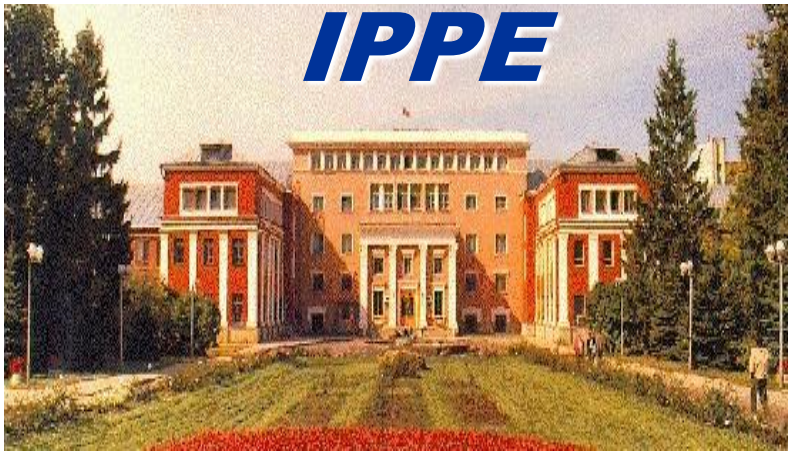
According to the Society of Nuclear Medicine (SNM), 13,407,500 cardiac perfusion studies, known as 'stress tests', were performed in 2009, to diagnose or exclude significant coronary artery disease. For 2010, SNM estimated 69,000 brain scans, 652,000 thyroid imaging and therapy procedures, 2,350,000 lung scans, 2,053,000 scans for diagnosis and monitoring of cancer and 3,255,000 bone scans.

The medical imaging consumables market is expected to grow at a CAGR of 14%, driven by persons 65 and over increasing twice as fast as the total population.

- Positron Emission Tomography (PET) detects radiographically occult lesions
- PET characterizes abnormalities difficult to biopsy
- PET is essential to be able to detect the primary tumor and distant sites of metastases, enabling treatment and staging
- PET evaluates the extent of cancer and response to therapy and changes cancer management in 36% of cases
- PET scans show molecular function and activity, not structure, and therefore can differentiate between normal and cancerous tumor tissue producing three dimensional images

Market Opportunity

- Large market with high barriers to entry, few competitors
- Specifically focused on generic radiopharmaceuticals and imaging agents
- Industry-recognized leader in development and cGMP manufacturing of radiopharmaceuticals and imaging agents
- Bio-Nucleonics' Cardiac Imaging Agent – awaiting FDA approval in 2012, $100 MM with only one competitor
- We have a strong pipeline of products (10 to be filed within the next two years)
- 18+ million nuclear medicine procedures using radiopharmaceuticals and imaging instruments are performed annually in the U.S. ‡
- Radiopharmaceutical benefits include:
  - Rapid diagnosis of problem conditions
  - Effective, immediate treatment
  - Reduced long-term medical/treatment expenses



РОСАТОМ

Institute of Physics and Power Engineering/ Research Institute of Atomic Reactors

Bio|Nucleonics™

Inspired by Innovative Ingenuity™

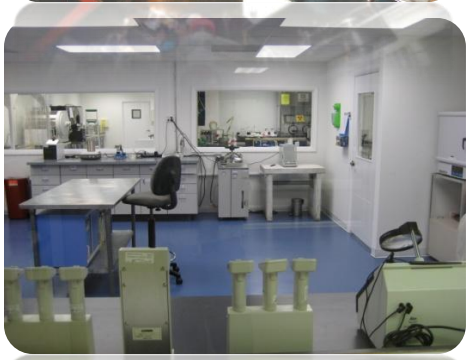
Company Overview

- Development, sales and cGMP manufacturing of radiopharmaceuticals and molecular imaging agents
- Founded in 1994
- Based in Doral, Florida
- 19 employees
- Management team with 85+ years of combined experience in the industry
- Regularly importing radioisotopes from Russia
- Clinical collaborations in the USA, EU, BRIC

Bio|Nucleonics™

Inspired by Innovative Ingenuity™

State of the Art Production Facilities



- The cGMP manufacturing complex consists of 17,000 Sq. Ft. of state-of-the-art laboratories and a Class 100 clean room suite in Doral, FL specifically designed for the manufacture of current and future products

- Bio-Nucleonics has held a Board of Pharmacy drug manufacturing license since 2005, in addition to being inspected and approved by the U.S. Food and Drug Administration, and has a radioactive license from the U.S. Nuclear Regulatory Commission

- Licenses enables the Company to perform cGMP development and production of radiopharmaceuticals, radioactive medical devices, companion diagnostics, molecular imaging agents and contract manufacturing

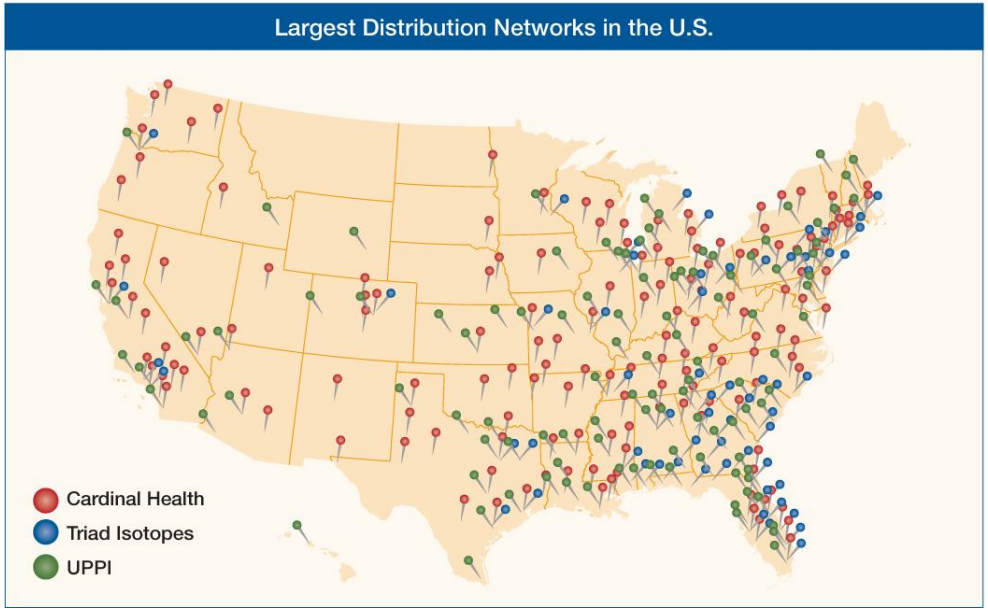
Strontium-89: The Project

- $50 MM U.S. cancer bone pain management market
  - Current market split between Sr-89), EUSA's Quadramet™ (Sm-153) and non-radioactive treatments or non-nuclear medicine alternatives (e.g., narcotic analgesics)
  - 90% of patient doses sold through radiopharmacy distribution channel
  - Average sale price (ASP) per dose is ~$3,000 to $5,000

- Strontium-89 is for patients with late stage cancer
  - Administered every 6 months to reduce bone pain associated with breast or prostate cancer that has spread to bone
  - Approved by the FDA in 2004; Launched 2006
  - Product manufacturing was shifted to a new facility
  - Strontium sales awaits FDA reinspection of the new facility which we anticipate in 60 days

- Near-term revenue expansion strategy:
  - Leveraging industry relationships
  - Establish formal performance-based supply agreements with the major radiopharmacy network players
  - Additional products in pipeline

Distribution Network



CardinalHealth
UPPI
Triad Isotopes
patient focused. | community driven.
petnet solutions
Department of Veterans Affairs
AnazaoHealth
Nuclear Medicine
Positron
NuView LIFE SCIENCES

- Bio-Nucleonics' distribution channels consist of the largest radiopharmacy networks with **350+ combined locations nationwide**
- Our network distributes 90% of all NM doses sold in U.S. and is eager for alternatives versus high priced brands
- High barriers for a new entrant to establish an alternative distribution network

Results of U.S.-Russian Collaborations and the Future

ISTC
CRDF
STCU
NIH
Enterprise Florida

CRDF
USIC
NSF
DOE
NNSA
U.S. Army
NIH
NATO

- Grants
- Exports/Imports
- First FDA Inspected and Approved cGMP API Facility in Russia
- Job Creation
- Conversion Grants
- New Products
- Improved Healthcare
- Better Quality-of Life of Patients
- New Cancer and Heart Disease Diagnostics
- New Therapeutics
- Increased Production of Medical Isotopes
- Driver of New Nuclear Medicine Facilities

Russia-EU working Group On Life Sciences, Genomics and Health; KBBE; bioNCP; Bilat-RUS; ACCESS-RU; CORDIS; EUREKA; KBBE Work Programme; Rusnano, Russian Venture Fund; Rosatom; etc.

How Much Does It Cost to Submit an Application to the FDA?

The Prescription Drug Act Filing Fee (PDUFA) for 2012, without which an FDA application will not be reviewed, is $1,850,500 with clinical trials or $920,750 without.

Once approved, an Establishment Fee of $520,100 and a Product Fee of $98,950 is also assessed.

These fees are in addition to drug development costs and in-vitro, preclinical and clinical trials.

Competing Technologies For Budget Money and Grants

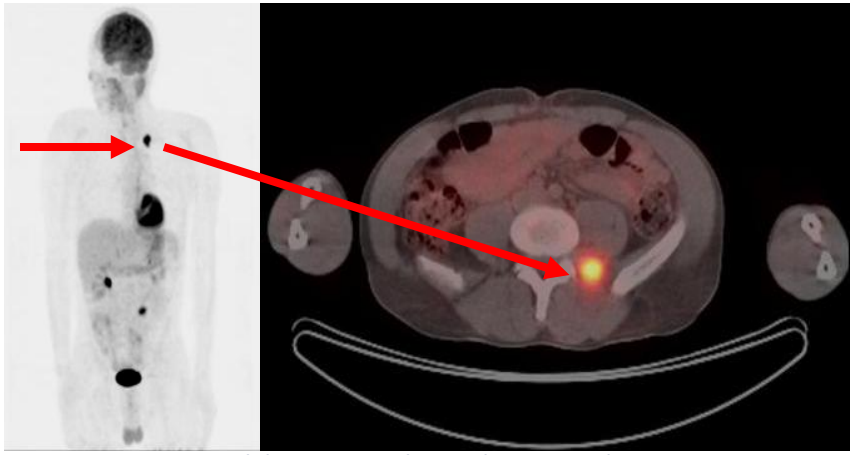
FIM 9 Stinger Missile = $35,000

Dose of Zevalin = $35,000

Every gun that is made, every warship launched, every rocket fired, signifies in the final sense a theft from those who hunger and are not fed, those who are cold and are not clothed.

Dwight D. Eisenhower

Competing Technologies For Budget Money and Grants

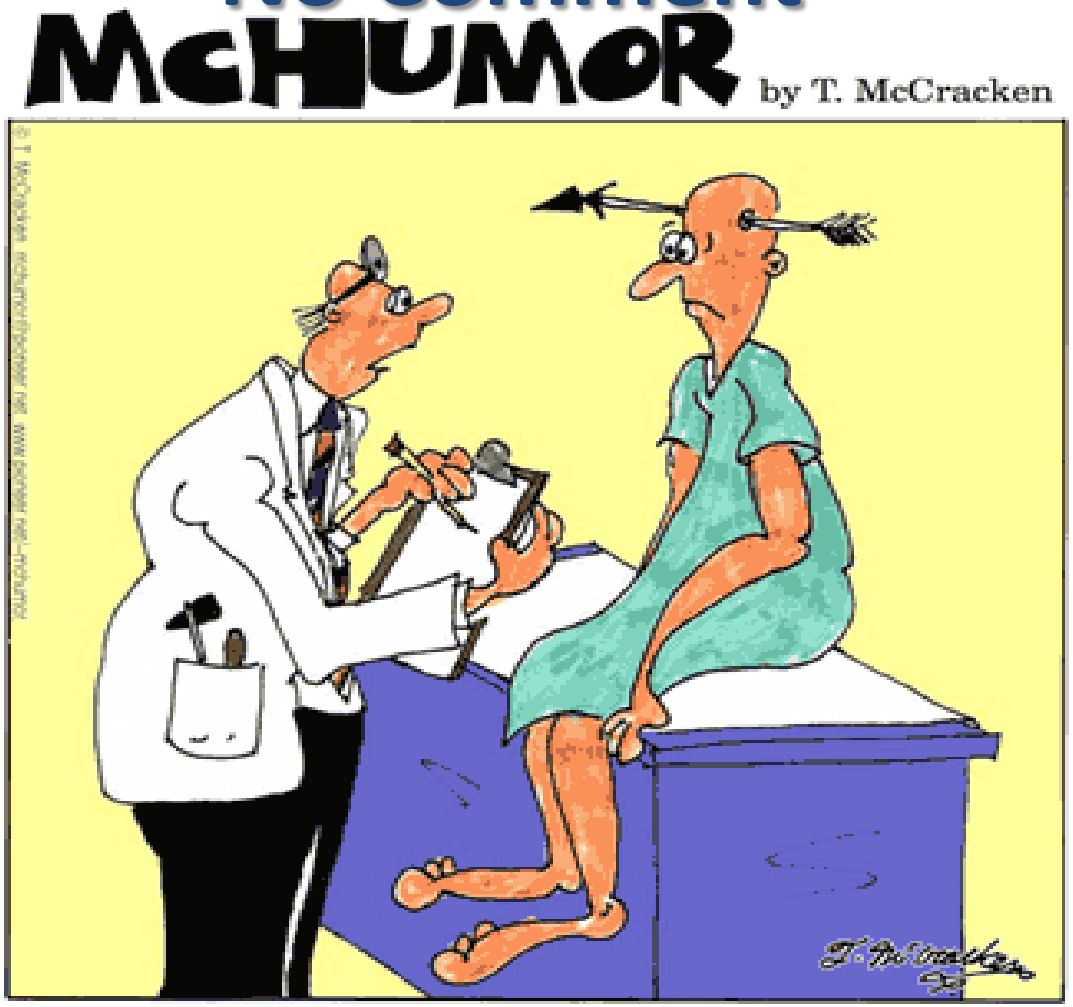


49 year old man with early stage lung cancer

Mark 48 Torpedo = $2.5 million

PET Scanner = $2.5 million

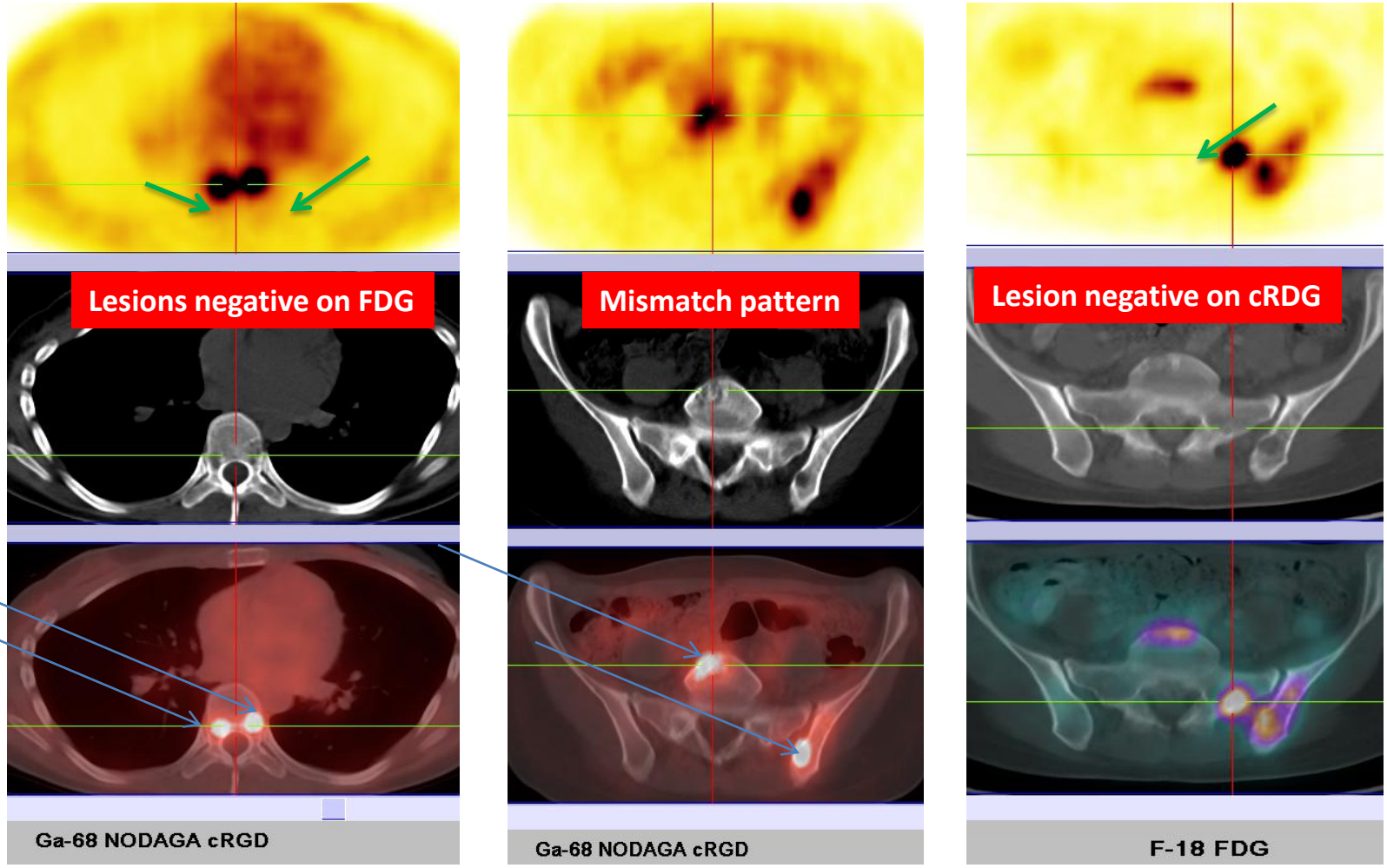
No Comment



"Off hand, I'd say you're suffering from an arrow through your head, but just to play it safe, I'm ordering a bunch of tests."

First-In-Human Study In a Breast Cancer Patient With Extensive Bone Metastases

Overall, 25 Integrin αvβ3 Positive Lesions Were Detected By THERANOST cRGD™ Versus 12 By ^{18}F FDG



MOLECULAR IMAGING OF TUMOR ANGIOGENESIS BY THERANOST cRGD™ VS. METABOLIC ^{18}F FDG

Courtesy of Prof. Dr. Richard Baum, Dept. of Nuclear Medicine/PET Center, Zentralklinik Bad Berka, Germany


Celebrating 30 Years of Excellence

GEN Genetic Engineering & Biotechnology News

Biotechnology from bench to business

Volume 31, Number 14 August 2011

IVD Sales in the BRIC Nations

$2.9

$5.0

OMICS | Drug Discovery | Translational Medicine | Bioprocessing | Biobusiness

aCGH Opens Up Novel Avenues of Study

Imaging Secures Development Role

Early Integration May Speed Progression of Drug Candidates through Pipeline

Josh P. Roberts

A B C

Companion diagnostics are molecular diagnostic tests for identifying patients who would respond best to therapeutics drugs.

A compound annual growth rate (CAGR) of 26.5% expected between 2011 and 2017 is projected for biomarker applications in clinical drug development, according to a September 2011 report by Global Industry Analysts (GIA). The growth rate is significant in an era of increased scrutiny by insurers in pre-authorization processes.

The clinical-development segment is growing rapidly, spurred in part because biomarkers help researchers identify and validate drug targets, hastening drug development. Oncology and cardiology are key areas targeted for growth.

This article in Genetic Engineering and Biotechnology News, underscores the importance of imaging and Theranostics and the role played in speeding up the development of new drugs such as therapies for Alzheimer's, stem cell therapies and a host of other diseases.

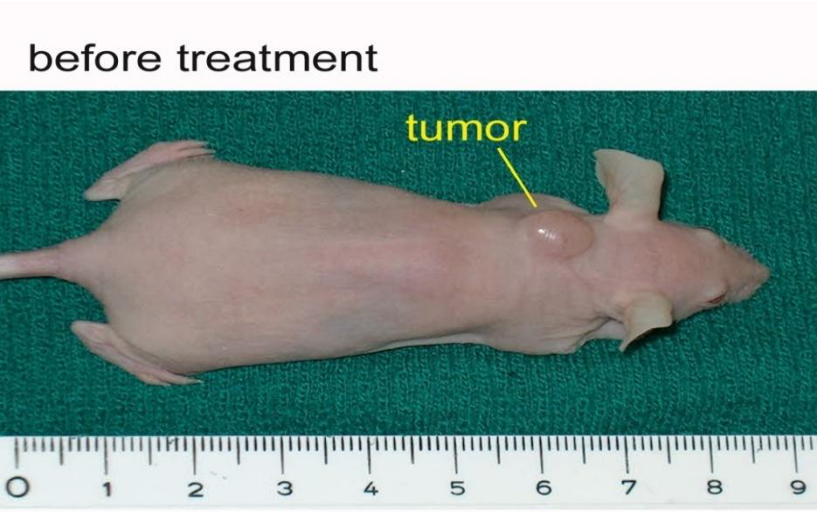
Progress Globally

Phase 1 eIND Clinical Trial Underway For Theranost RGD™, PET Imaging to Detect Tumors and Angiogenesis, and For Peptide Receptor Radionuclide Combination Therapy

Organizing Multi-Center Clinical Trials

Phase 1 Clinical Trial of AtheroPET™ , For PET Imaging to Detect Early Stage Atherosclerosis, to Differentiate Stable from Vulnerable Plaque and detect abdominal aortic aneurysms (AAA)

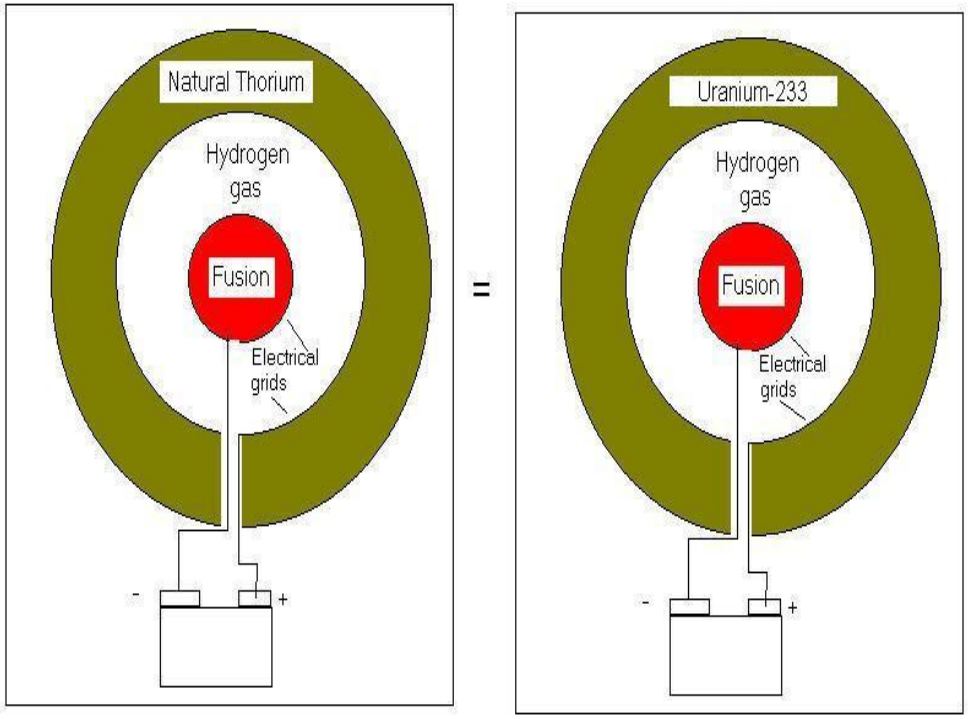
Nanoparticle Peptide Receptor Radionuclide Therapy

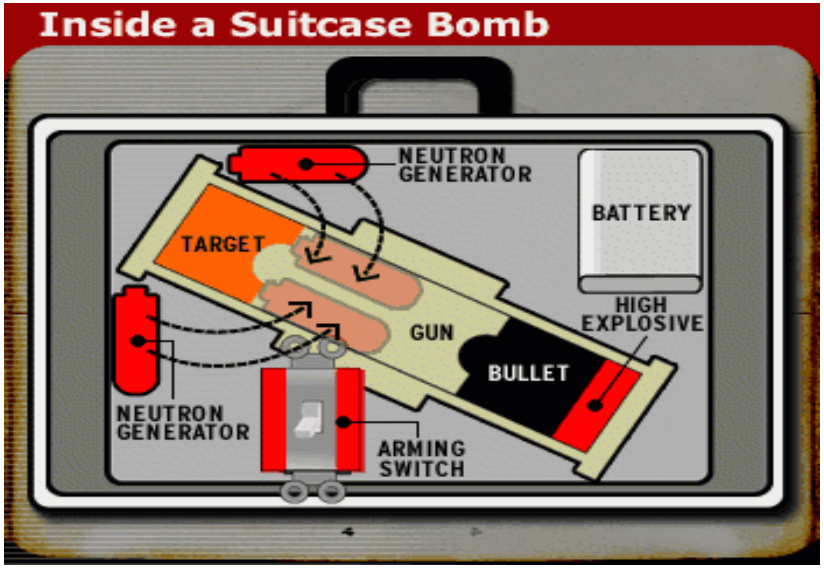


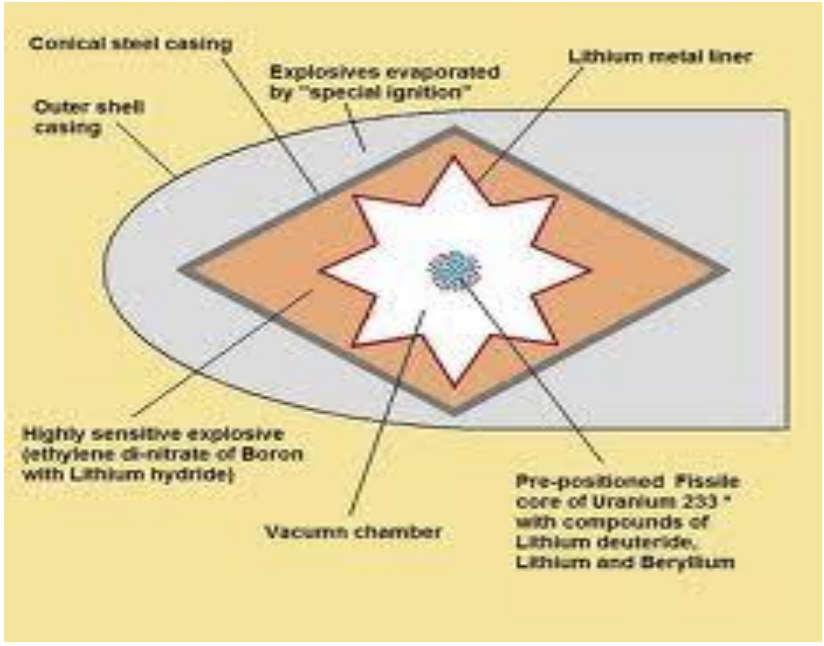
- Cancer is not one disease. It is many. Yet oncologists have long used the same blunt weapons to fight different types of cancer: cut the tumor out, zap it with radiation or blast it with chemotherapy that kills good cells as well as bad ones.
- Radionuclide therapy is a unique treatment modality lying between chemotherapy and external radiotherapy.
- The challenge for the next years is to select the most promising and appropriate targets for (pre-)clinical use, while at the same time optimally integrate its unique capabilities into the increasing number of other anti-cancer treatment strategies available.
- Targeted radionuclide therapy involves the use of radiolabeled tumor-seeking molecules to deliver a cytotoxic dose of radiation to tumor cells.
- An important difference between targeted radionuclide therapy and external beam irradiation is the finite range of ionizing particles emitted.

Found: Do-It-Yourself Fissile Material Production and Compact Nuclear Device

HOW TO MAKE URANIUM-233







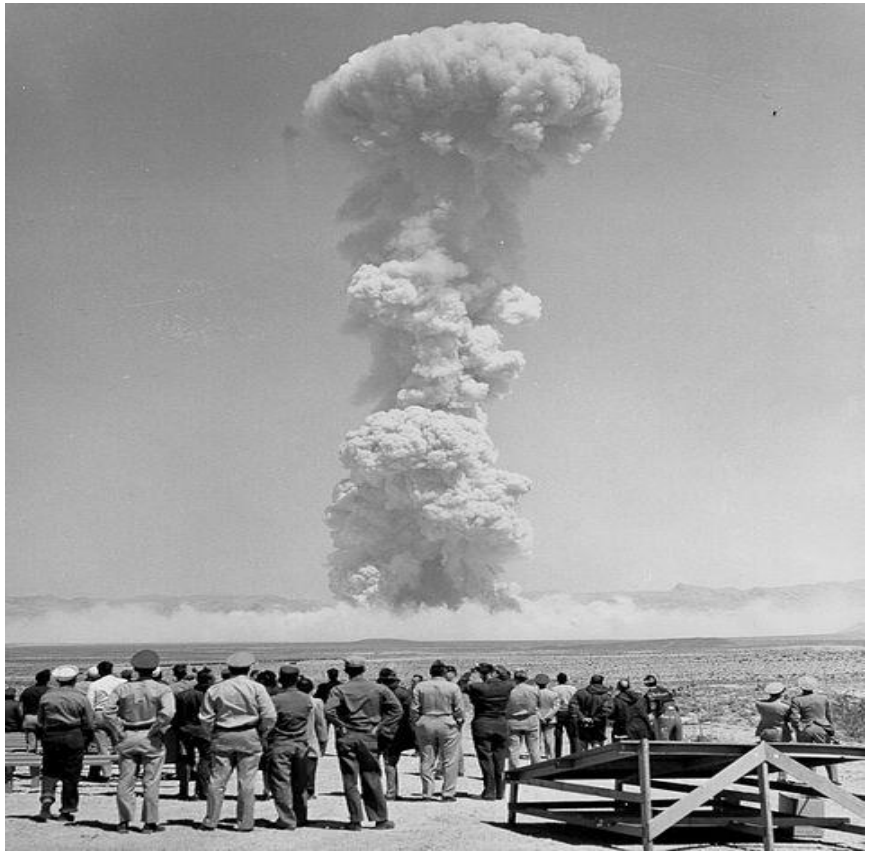
Here again the postive grid strips the electrons from the hydrogen gas and the negative attracts the ions into the center. When two protons collide a neutron is created and thrown randomly out. Fusion is created by this process. The nuclear material is enriched and transmuted into another element.

Why the average person may not be able to make Uranium-235 for a nuclear bomb it is possible for the average person to make Uranium-233 with the dirt out of their own back yard. Thorium averages 12 parts per million over much of the earth and in some places averages about 12 percent of the material. It is one of the most common elements on earth. So, simply mine some thorium out of your own back yard or buy it from a chemical supply house. Build a simple fuser unit or other neutron source. Pack it with thorium and hydrogen gas. Run it day and night with radiation shielding of course. Thorium makes a good radiation shield but put that on the outside not the inside. In time you will have the best fission material for making a nuclear bomb on the face of the entire earth. Simply pack explosives around it to set it off.

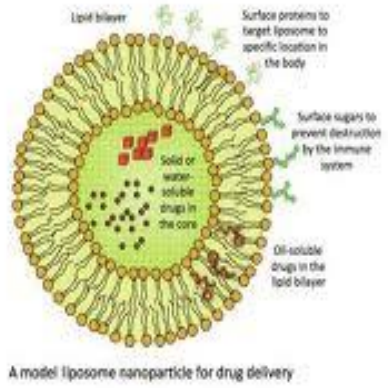
This may not be legal to do where you live. Before attempting anything like this talk to your responsible authorities. Tell them your plans and get their permission first. Also, talk to your local experts after getting approval. Please don't play with anything like this at home boys and girls.

The U.S. produced, over the course of the cold war, approximately 2 metric tons of uranium-233, in varying levels of chemical and isotopic purity. So did Russia.

Uses for uranium-233 include production of medical isotopes actinium-225 and bismuth-213. The radioisotope bismuth-213 is a decay product of uranium-233; it has promise for the radioimmuno-therapy treatment of certain types of cancer, including acute myeloid leukemia and cancers of the pancreas, kidneys and other organs as well as HIV/AIDS.



The first detonation of a nuclear bomb involving U-233, on 15 April 1955



A model liposome nanoparticle for drug delivery

Cancer Res. 2009 Dec 1;69(23):8941-8. Epub 2009 Nov 17.

Radioimmunotherapy of breast cancer metastases with alpha-particle emitter 225Ac: comparing efficacy with 213Bi and 90Y.

Song H, Hobbs RF, Vajravelu R, Huso DL, Esaias C, Apostolidis C, Morgenstern A, Sgouros G.

Source

Division of Nuclear Medicine, Russell H. Morgan Department of Radiology, Johns Hopkins University School of Medicine, Baltimore, Maryland 21231, USA.

Abstract

alpha-Particles are suitable to treat cancer micrometastases because of their short range and very high linear energy transfer. alpha-Particle emitter (213)Bi-based

Cancer Res. 2010 Sep 1;70(17):6815-23. Epub 2010 Jul 22.

Immunoliposomal delivery of 213Bi for alpha-emitter targeting of metastatic breast cancer.

Lingappa M, Song H, Thompson S, Bruchertseifer F, Morgenstern A, Sgouros G.

Source

Russell H. Morgan Department of Radiology and Radiological Science, Johns Hopkins University, Baltimore, MD, USA.

Abstract

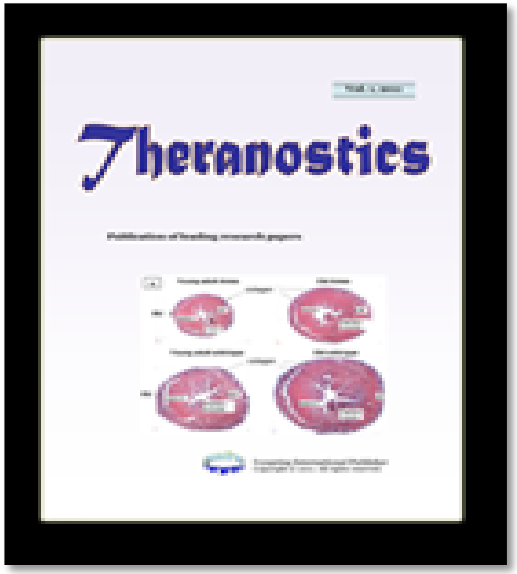
Current treatment for late-stage metastatic breast cancer is largely palliative. alpha-Particles are highly potent, short-range radiation emissions capable of sterilizing individual cells with one to three traversals of the cell nucleus. The alpha-emitter, (213)Bi (T(1/2) = 45.6 min), was conjugated to a 100-nm diameter liposomal-CHX-A''-DTPA construct, upon which the rat HER2/neu reactive antibody, 7.16.4, was grafted. A conjugation time of 10 minutes was achieved giving a specific activity corresponding to 0.1 (213)Bi atom per liposome; stability in vitro and in vivo was confirmed. Efficacy in a rat/neu transgenic mouse model of metastatic mammary carcinoma was investigated. Three days after left cardiac ventricular injection of 10(5) rat HER-2/neu-expressing syngeneic tumor cells.

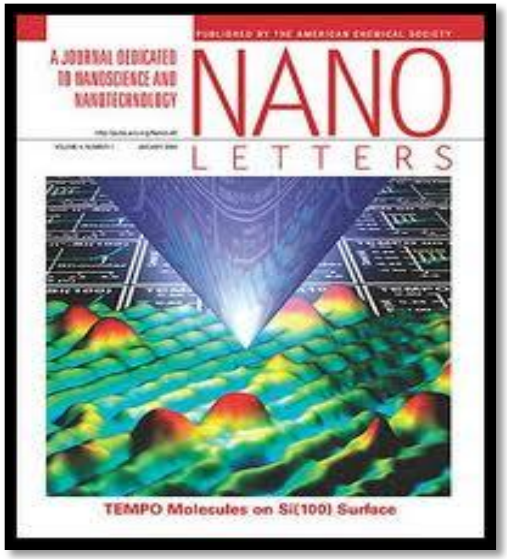
Radioimmunotherapy has shown efficacy in a variety of metastatic animal cancer models, such as breast, ovarian, and prostate cancers. Its clinical implementation, however, is challenging due to the limited supply of (225)Ac, high technical requirement to prepare radioimmunoconjugate with very short half-life (T(1/2) = 45.6 min) on site, and prohibitive cost. In this study, we investigated the efficacy of the alpha-particle emitter (225)Ac, parent of (213)Bi, in a mouse model of breast cancer metastases.

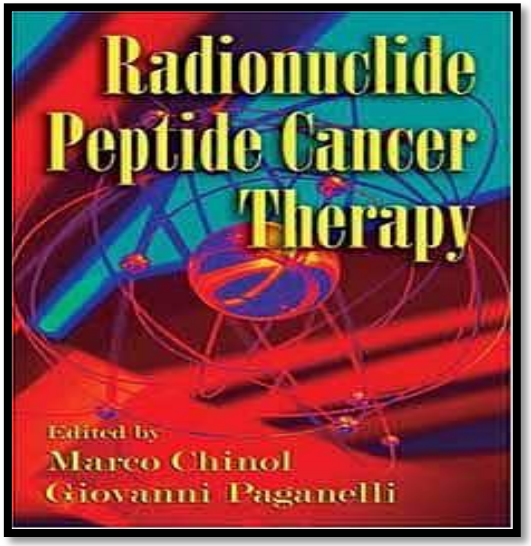
A single administration of (225)Ac (400 nCi)-labeled anti-rat HER-2/neu monoclonal antibody (7.16.4) completely eradicated breast cancer lung micrometastases in approximately 67% of HER-2/neu transgenic mice and led to long-term survival of these mice for up to 1 year.

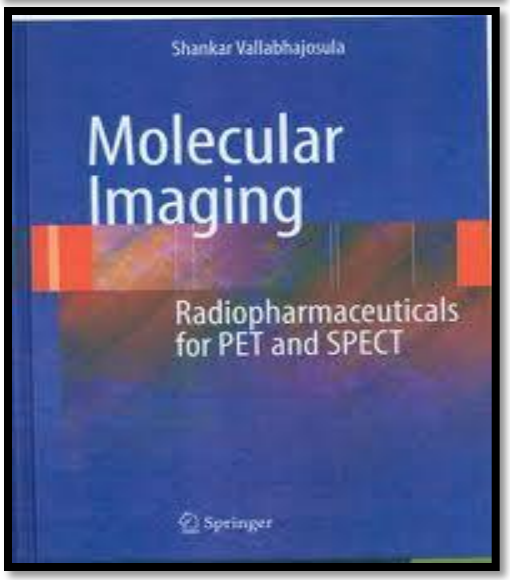
Treatment with (225)Ac-7.16.4 is significantly more effective than (213)Bi-7.16.4 (120 microCi; median survival, 61 days; $P = 0.001$) and (90)Y-7.16.4 (120 microCi; median survival, 50 days; $P < 0.001$) as well as untreated control (median survival, 41 days; $P < 0.0001$). Dosimetric analysis showed that (225)Ac-treated metastases received a total dose of 9.6 Gy, significantly higher than 2.0 Gy from (213)Bi and 2.4 Gy from (90)Y. Biodistribution studies revealed that (225)Ac daughters, (221)Fr and (213)Bi, accumulated in kidneys and probably contributed to the long-term renal toxicity observed in surviving mice. These data suggest (225)Ac-labeled anti-HER-2/neu monoclonal antibody could significantly prolong survival in HER-2/neu-positive metastatic breast cancer patients

Periodicals and Publications









Lilly

Lilly ($LLY) snags Avid Radiopharmaceuticals in $800M buyout deal

Frustrated by a series of nasty setbacks in the clinic, pharma giant Eli Lilly ($LLY) is writing a $300 million check to acquire Avid Radiopharmaceuticals, a diagnostics company that has garnered worldwide attention for its new approach to detecting Alzheimer's. Lilly also is promising to pay an additional $500 million provided flor-betapir hits certain regulatory and commercial milestones.

Abbott pays $400M Cash in Preclinical Deal

December 12, 2011 — 8:12am ET | By John Carroll

Abbott ($ABT) agreed to plunk down $400 million in cash to gain an equal stake in the worldwide rights to a portfolio of Reata's promising second-generation compounds now in preclinical development for a range of conditions.

Bayer snares Algeta's lead cancer med in $800M pact

September 3, 2009 — 8:09am ET | By John Carroll

In a fresh sign of just how hot cancer meds have become, Bayer Schering Pharma took analysts by surprise this morning with an $800 million licensing pact for Algeta's lead drug--an experimental therapy that targets cancerous bone cells. Bayer will pay $61 million of that upfront for Alpharadin, a prospective blockbuster which uses alpha rays to eliminate cancer cells.

Norway's Algeta also stands to earn double-digit royalties on sales of Alpharadin and has an option to switch from royalties to a split of the profits in the U.S. market. "This is an extremely positive deal, the size is significant and far larger than what we had expected," DnB NOR Markets analyst Espen Joergensen commented.

Free newsletter via e-mail

ImmunoGen and Lilly unite to develop cancer treatments

ImmunoGen and Eli Lilly and Co. agreed to jointly develop antibody-based cancer drugs in a deal worth at least $20 million. The agreement gives Lilly exclusive licensing rights to some of ImmunoGen's cancer drugs in exchange for a $200 million milestone fee for each drug licensed as well as royalties on any product developed through the partnership. Maytansinoid targeted antibody payload technology developed by ImmunoGen delivers drugs straight to cancer cells. The Wall Street Journal/Dow Jones Newswires

Fresenius to Buy APP Pharmaceuticals

BY DEALBOOK

Fresenius, the giant German maker of dialysis services and products, said Monday that it will buy APP Pharmaceuticals for for about $4.6 billion including debt, giving it control of one of the biggest makers of generic injectable drugs.

Fujifilm to buy SonoSite for nearly $1B

Fujifilm Holdings has entered into a definitive agreement with SonoSite.

J&J's Jannsen Biotech/Pharmacyclics and Molecular Partners in Two $800 million Deals

Janssen, a unit of Johnson & Johnson ($JNJ) has made big bet on the future of developer Pharmacyclics' ($PCYC) experimental compound in midstage testing for blood cancers, shelling out $150 million in upfront money to seal the deal and promising up to $825 million in milestone payments. While the pact may be a small piece of the pipeline puzzle at the healthcare giant J&J, it's a significant step forward for Sunnyvale, CA-based Pharmacyclics, which has no products on the market and failed to get FDA approval of a previous cancer drug. Pharmacyclics now has a deep-pocketed development partner to advance PCI-32765, a Bruton's tyrosine kinase (Btk) inhibitor.

Hospira agrees to buy Mayne Pharma for $2 billion

By Ana Campoy, MarketWatch

SAN FRANCISCO (MarketWatch) -- Hospira Inc. late Wednesday said it has agreed to buy Australian generic pharmaceuticals maker Mayne Pharma Ltd. in an effort to expand its international operations and its cancer drug portfolio.

Lake Forest, Ill.-based Hospira HSP +0.27% will pay $2 billion, or 4.10 a share in Australian dollars ($3.09), including options, for Mayne. That represents a 32% premium over Mayne's Sept. 18 closing price.

Teva closes SICOR acquisition

Israel-headquartered generics company Teva Pharmaceutical Industries has completed its $3.4 billion takeover of US company SICOR, which makes generics and active pharmaceutical ingredients.

Novartis completes Sabex acquisition

Provides strong growth opportunities in generic injectables market

Basel, 16 August 2004 – Novartis AG announced today that its Sandoz generics business unit has completed the acquisition of Sabex Holdings Ltd., a leading Canadian generics pharmaceutical manufacturer in a USD 565 million cash transaction that officially closed on August 13. Sabex was acquired from the US private equity firm RoundTable Healthcare Partners, which had held a majority stake in the company.

GE Acquires Amersham For $9.5 Billion

800p per share Offer in All Stock Transaction

LONDON/FAIRFIELD, CT - General Electric Company and Amersham plc today announced that, subject to regulatory approval and other customary conditions, they have reached agreement on the terms of an all-stock transaction whereby GE (via General Electric Company and GE Investments, Inc.) will acquire all the outstanding shares of Amersham, a world leader in diagnostic imaging agents and life sciences. The terms of the transaction value each Amersham share at 800 pence and the diluted share capital of Amersham at approximately £5.7 billion ($9.5 billion).

Gilead Acquires Pharmasset For $11 billion

The $11 billion Gilead Sciences paid for Pharmasset and its promising Phase II nucleoside polymerase inhibitor for treatment of Hepatitis C on Nov. 21 opened eyes, but also sparked a great deal of speculation. Particularly, what would this record-shattering deal mean for other biotechs with un-partnered candidates? There's speculation that it was a competitive process to get Pharmasset, so presumably there's more than one company willing to pay a big number.

Russia investing in two Mass. start-ups

Government fund to contribute $50m to biomedical companies

By *Robert Weisman*
| Boston Globe Staff October 28, 2011

European and Japanese drug makers have been beating a path to the Boston area's flourishing biomedical labs for the past decade, setting up outposts, striking partnerships with academic researchers, and buying local biotechnology start-ups.

Now they are being joined by a new entrant in life sciences investing: the government of Russia, a country better known for oil and vodka than for breakthrough therapeutics.

In one of the largest financing rounds this year for area companies, Rusnano, a Russian Federation fund that backs nanotechnology ventures, yesterday said it will contribute $50 million to a total pool of $94.5 million for two start-ups that are using nanomedicine - the medical application of molecular-scale particles - to develop cutting-edge drugs.

Two Boston-area startups—both of which emanated from the lab of MIT bioengineer and entrepreneur Bob Langer—announced today that they secured $25 million apiece in funding from Rusnano, a $10 billion Russian Federation fund that supports nanotechnology startups.

The companies, BIND Biosciences Inc. of Cambridge and Selecta Biosciences Inc. of Watertown, both use technology that originated in Massachusetts Institute of Technology labs directed by professor Robert S. Langer and in Harvard Medical School labs run by professor Omid C. Farokhzad. Farokhzad and Langer, a recipient of the US National Medal of Science, are cofounders of the two companies.

As part of the deal, which also includes new private investors and previous backers making fresh investments, BIND and Selecta will establish subsidiaries in Russia, which is seeking to use its chemical-engineering expertise to boost its life sciences industry.

"This gives us the resources and the access to some unique capabilities here in Russia,'' BIND chief executive Scott Minick said from Moscow, where the plans were unveiled. "Russia is a very good place to do research and clinical studies.''

BIND and Selecta aren't the first Boston area companies to establish footholds in Russia - biotechnology giant Genzyme, a division of Sanofi SA, has an operation there - but the start-ups are hoping their collaboration with the Russian government through its $10 billion Rusnano fund will pay business dividends there and elsewhere.

The Skolkovo Innovation Center, a high-tech industrial park some 15 kilometers west of Moscow's city center modeled on California's Silicon Valley, is scheduled for completion by 2015. International corporations who have announced ventures in Skolkovo include Microsoft, RWE, Intel, Nokia, Siemens, Boeing and Tata. The Russian government has allocated funding of US $2.8 billion to the project for its first three years alone. Construction is scheduled to begin in the second half of 2011.

Bio|Nucleonics™

Inspired by Innovative Ingenuity™

Bio-Nucleonics' Development Team, Very Hard at Work Here In Miami

Contemplating Preclinical And Clinical Validation Of Molecular Imaging Agents, Alpha Emitters for Radioimmunotherapy and Products for Peptide Receptor Radionuclide Therapy

Collaborators

- Alejandro Amor, MBA, Radiochemist, Bio-Nucleonics, Inc., Miami, FL
- Prof. Dr. Richard Baum, Chairman, and Clinical Director, Department of Nuclear Medicine, Central Clinic, Bad Berka, Germany
- Narasimhan Danthi, Ph.D., Director, Molecular Imaging Laboratory, National Institutes of Health, Bethesda, MD
- Martin Brechbiel, Ph.D., Radiation Oncology Branch, *Head, Radioimmune Inorganic Chemistry Section,* Sr. Investigator NIH, Bethesda, MD
- Cathy Cutler, Ph.D., Sr. Research Scientist, University of Missouri, Missouri University Research Reactor, Columbia, MO
- Dario Echeverri, MD, Director of Cardiology Vascular Function Laboratory, Children's Cardiac Hospital Foundation, Bogotá, Colombia
- Stefano Fanti, M.D. Director of Nuclear Medicine, University of Bologna, Bologna, Italy
- Gregg Fields, Ph.D. Chairman, Department of Biochemistry, Florida Atlantic University, Boca Raton, FL
- Jorge Flores, Radiation Safety Officer and Radiochemist,Bio-Nucleonics, Inc., Miami, FL
- Ahmed Gharib, M.D., MB, ChB, Staff Clinician, National Institutes of Health, Bethesda, MD
- Seza Gulec, M.D., Director of Surgical and Nuclear Oncology Research, Jackson Memorial Hospital, FIU College of Medicine, Miami, FL
- Joshua M. Hare, M.D., Chief, Division of Cardiology, Director, Stem Cell Institute, University of Miami, Miami, FL
- Julie Heroux, M.Sc., Laboratory Manager, National Institutes of Health, Bethesda, MD
- Luis Iga, Vice President, Bio-Nucleonics, Inc.
- Warren R. Janowitz, M.D., JD, Director of Nuclear Medicine, Baptist Hospital and Cardiac and Vascular Institute, Miami, FL
- Bernward Lauer, M.D., Medical Director, Central Hospital, and Director of the Cardiological Clinic Heart Center, Bad Berka, Germany
- Marlies Lopez, CNMT, and Radiochemist, Bio-Nucleonics, Inc., Miami, FL
- James Margolis, M.D., Miami Interventional Cardiology Consultants, Inc., Jackson Health System, Miami, FL
- Alexander (Sandy) McEwan, M.D., Cross Cancer Institute, Edmonton, Canada
- James B. Nichols, D.V.M., M.S., Director of Veterinary Services, Florida Atlantic University, Boca Raton, FL
- Semih Oktay, Ph.D., President, CardioMed Device Consultants, Baltimore, MD
- John O. Prior, Ph.D., M.D., Professor and Chairman of Nuclear Medicine, CHUV University Hospital, Lausanne, Switzerland
- Rosanne Satz, President and CEO, Bio-Nucleonics, Inc. Miami, FL
- Roger Schibli, Ph.D., ETH Swiss Federal Institute of Technology, Zurich and Paul Scherrer Institute, Villagen,Switzerland
- Vladimir B. Sergienko, M.D., Director, Department of Nuclear Medicine, Russian Cardiology Research Center, Moscow, Russia
- Michael Shen, M.D., M.S., Head of Cardiac Imaging, Cleveland Clinic, Weston, FL
- Michael Stabin, Ph.D. Associate Professor, Department of Radiology and Radiological Sciences, Vanderbilt University, Nashville, TN.
- Henry Wagner, M.D., Professor Emeritus, Johns Hopkins University, Baltimore, MD
- Sergio Waxman, M.D., Director, Interventional Cardiology Research, Lahey Clinic, Professor of Medicine, Tufts University, Burlington, MA
- Irina Velikyan, Ph.D. Center for Medical Imaging, Uppsala University Hospiital, Uppsala, Sweden
- Nikolai Nerozin, Ph.D., Head of Research and Production Complex , Institute of Physics and Power Engineering, Obninsk, Russia
- Valery Rachkov, Ph.D. Director General, Institute of Physics and Power Engineering, Obninsk, Russia
- Alavi Abass, M.D. Hospital of the University of Pennsylvania, Philadelphia, PA
- Josef Machac, M.D., Mount Sinai Medical Center, New York, NY
- Zahi Fayad, M.D., Mount Sinai Medical Center, New York, NY
- Eric Liu, M.D. Department of Surgery, Vanderbilt University Medical Center, Knoxville, TN

People never lie so much as after a hunt, during a war or before an election.
Otto von Bismarck